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10/764,974	01/26/2004	Gary T. Neel	06882.0095-00	9318

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EXAMINER

WOODS, TERESA S

ART UNIT	PAPER NUMBER
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4114

MAIL DATE	DELIVERY MODE
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02/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/764,974	Applicant(s) NEEL ET AL.	
	Examiner TERESA WOODS	Art Unit 4114	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/14/05, 5/4/05, 7/20/04 & 1/26/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 01/26/2004.
2. Claims 1-30 are currently pending and have been examined.

Information Disclosure Statement

3. The Information Disclosure Statements filed 1/26/2004, 7/20/2004, 5/4/2005 and 6/14/2005 have been considered. Initialed copies of the Form 1449 are enclosed herewith.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ciurczak (US 2002019367 A1).

6. **Claim 1:**

Ciurczak discloses the limitations as shown below:

- *obtaining a test result using said medical diagnostic testing device (C, see at least ¶0030);*
- *storing said test result in said medical diagnostic testing device (C, see at least ¶0030);*

This reference shows how a computer is used as a storing device to store data with a patient's glucose level.

- *recording a voice message, associated with said test result, in said medical diagnostic test device (C, see at least ¶0101).*

This reference shows how a voice recognition feature is used as a transmission mechanism between a diabetic patient and a doctor.

7. **Claim 12:**

Ciurczak discloses the limitations as shown below:

- *a testing system for obtaining a test result (C, see at least ¶0030);*
- *a memory for storing said test result (C, see at least ¶0030);*

This reference shows how a computer is used as a storing device to store data with a patient's glucose level.

- *an audio system for recording a voice message associated with said test result (C, see at least ¶0101).*

This reference shows how a voice recognition feature is used as a transmission mechanism between a diabetic patient and a doctor.

8. Claim 14:

Ciurczak discloses the limitations as shown below:

- *a measurement system for interacting with said test strip, with a sample applied thereto, to obtain at least one measurement; and (see at least ¶0096)*
- *a controller for controlling said measurement system, said controller determining said test result based on said at least one measurement (see at least ¶0096) .*

In this reference, the measurement system used as the controller is a electrochemical detector.

9. Claims 25, 27, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilcox (US 20050002483 A1).

10. Claim 25:

Wilcox discloses the limitations as shown below:

- *an audio system for recording a voice message associated with a test result(C, see at least ¶0101).*

This reference shows how a voice recognition feature is used as a transmission

mechanism between a diabetic patient and a doctor.

11. Claim 27:

Wilcox discloses the limitations as shown below:

- *wherein said audio system includes digital storage for digitally storing a recorded voice message (W, see at least Fig. 3, ¶0009).*

12. Claim 29:

Wilcox discloses the limitations as shown below:

- *a user interface for receiving a record instruction, wherein said medical diagnostic testing device records said voice message in response to said record instruction (W, see at least Fig. 3, ¶0009).*

In this reference, the computer is the testing device, the computer program is the means to receive instructions, the study is the test result and images are interpreted using voice recognition software.

13. Claim 30:

Wilcox discloses the limitations as shown below:

- *a user interface for receiving a retrieve instruction, wherein said medical diagnostic testing device displays a stored test result and plays a recorded voice message associated with said stored test result in response to said retrieve instruction (W, see at least Fig. 2, ¶0009, ¶0016).*

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 2, 4, 5-7, 13, 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ciurczak (US 2002019367 A1) in view of Cunningham (US 6,306,104 B1).

17. **Claim 2:**

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation, but Cunningham discloses the following limitations:

- *applying a sample to a test strip* (see at least column 1, lines 41-48);

- *said medical diagnostic testing device interacting with said test strip, with said sample applied thereto, to obtain at least one measurement; and (see at least column 1, lines 41-48)*
- *determining said test result based on said at least one measurement (see at least column 1, lines 41-48).*

This reference describes a glucose monitoring device that utilizes test strips to determine the glucose level in blood. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Cunningham's interacting test strips with Ciurczak's medical diagnostic testing device to provide a user-friendly way to perform any self-diagnosis tests and get results quickly. This would help to improve the quality of self-medical care for others.

18. Claim 4:

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation, but Cunningham discloses *wherein said test result is a glucose level in said sample* (see at least column 1, lines 41-48). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Cunningham's glucose level results with Ciurczak's medical diagnostic testing device to provide the basic glucose concentration in the blood stream of diabetic patients. This would continue to help improve the quality of self-medical care for others.

19. Claim 5:

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation, but Cunningham discloses *wherein said at least one measurement includes an optical measurement* (see at least Fig. 5, column 18, lines 9-11). This reference has a display screen to visibly see the measured results. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Cunningham's displayable results with Ciurczak's medical diagnostic testing device to provide a user-friendly way to perform any self-diagnosis tests and get results quickly. This would help to improve the quality of self-medical care for others.

20. Claim 6:

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation, but Cunningham discloses *wherein said at least one measurement includes an electrical measurement* (see at least Fig. 11A, column 25, lines 18-24). This reference describes electric contacts that are used to detect the glucose. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Cunningham's electric contacts with Ciurczak's medical diagnostic testing device to provide an efficient way to perform self-diagnosis tests and get results quickly. This would help to improve the quality of self-medical care for others.

21. Claim 7:

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation, but Cunningham discloses *said medical diagnostic testing device displaying said test result* (see at least Fig. 5-14, column 25, lines 55-60). This reference has a display screen to visibly see the measured results. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Cunningham's displayable results with Ciurczak's medical diagnostic testing device to provide a user-friendly way to perform any self-diagnosis tests and get results quickly. This would help to improve the quality of self-medical care for others.

22. Claim 13:

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation, but Cunningham discloses *a test strip interface for receiving a test strip* (see at least column 1, lines 41-48). This reference describes a glucose monitoring device that utilizes test strips to determine the glucose level in blood. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Cunningham's interacting test strips with Ciurczak's medical diagnostic testing device to provide a user-friendly way to perform any self-diagnosis tests and get results quickly. This would help to improve the quality of self-medical care for others.

23. Claim 17:

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation, but Cunningham discloses *wherein said at least one measurement includes an optical measurement* (see at least Fig. 5, column 18, lines 9-11). This reference has a display screen to visibly see the measured results. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Cunningham's displayable results with Ciurczak's medical diagnostic testing device to provide a user-friendly way to perform any self-diagnosis tests and get results quickly. This would help to improve the quality of self-medical care for others.

24. Claim 18:

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation, but Cunningham discloses *wherein said at least one measurement includes an electrical measurement* (see at least Fig. 11A, column 25, lines 18-24). This reference describes electric contacts that are used to detect the glucose. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Cunningham's electric contacts with Ciurczak's medical diagnostic testing device to provide an efficient way to perform self-diagnosis tests and get results quickly. This would help to improve the quality of self-medical care for others.

25. **Claim 19:**

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation, but Cunningham discloses *said medical diagnostic testing device displaying said test result* (see at least Fig. 5-14, column 25, lines 55-60). This reference has a display screen to visibly see the measured results. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Cunningham's displayable results with Ciurczak's medical diagnostic testing device to provide a user-friendly way to perform any self-diagnosis tests and get results quickly. This would help to improve the quality of self-medical care for others.

26. Claims 3, 15, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ciurczak (US 2002019367 A1) in view of Official Notice.

27. **Claim 3:**

Ciurczak discloses limitations as shown in the rejections above. Ciurczak does not disclose *wherein said sample is whole blood*. However, the Examiner takes **Official Notice** that it is old and well-known in the medical arts that the analysis of human blood is referred to as whole blood. It would have been obvious to a person having ordinary skill in the art at the time of invention to combine whole blood with Ciurczak's medical diagnostic testing device to provide a more comprehensive glucose monitoring device. This would continue to help improve the quality of self-medical care for diabetic patients.

28. Claim 15:

Ciurczak discloses limitations as shown in the rejections above. Ciurczak does not disclose *wherein said sample is whole blood*. However, the Examiner takes **Official Notice** that it is old and well-known in the medical arts that the analysis of human blood is referred to as whole blood. It would have been obvious to a person having ordinary skill in the art at the time of invention to combine whole blood with Ciurczak's medical diagnostic testing device with a its controller to provide a more comprehensive glucose monitoring device. This would continue to help improve the quality of self-medical care for diabetic patients.

29. Claim 20 and 21:

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation:

- *a microphone for receiving said voice message;*
- *a digital sampler to provide digital samples of said voice message;*
- *digital storage for storing said digital samples of said voice message*
- *wherein said audio system further comprises: a speaker for playing said voice message stored in said digital storage.*

However, the Examiner takes **Official Notice** that it is old and well-known in the electronics arts that the components, used in audio systems, are microphones, digital voice samples, and voice recordings. It would have been

Art Unit: 4114

obvious to a person having ordinary skill in the art at the time of invention to combine audio components with Ciurczak's diagnostic testing device to provide a more comprehensive glucose monitoring device. This would continue to help improve the quality of self-medical care for diabetic patients.

30. Claims 8-11 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ciurczak (US 2002019367 A1) in view of Wilcox (US 20050002483 A1).

31. **Claim 8:**

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation, but Wilcox discloses *said medical diagnostic testing device displaying a stored test result* (see at least Fig. 2, ¶0016). In this reference, the test results are radiology images stored on an image web server. It would have been obvious to a person having ordinary skill in the art at the time of invention to combine Wilcox's displayable stored test results with Ciurczak's diagnostic testing device to provide a more comprehensive glucose monitoring device. This would continue to help improve the quality of self-medical care for diabetic patients.

32. Claim 9:

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation, but Wilcox discloses *said medical diagnostic testing device playing a recorded voice message* (see at least Fig. 3, ¶0009). In this reference, the recorded voice message is the interpretation of diagnosed images. It would have been obvious to a person having ordinary skill in the art at the time of invention to combine Wilcox's voice message with Ciurczak's diagnostic testing device to provide a more comprehensive glucose monitoring device. This would continue to help improve the quality of self-medical care for diabetic patients.

33. Claim 10:

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation, but Wilcox discloses *said medical diagnostic testing device receiving a retrieve instruction; and in response to said retrieve instruction, said medical diagnostic testing device displaying a stored test result and playing a recorded voice message associated with said stored test result* (see at least ¶0017, claim 6). In this reference, the computer is the testing device and the computer program serves as the way a user receives instructions. It would have been obvious to a person having ordinary skill in the art at the time of invention to combine Wilcox's stored and retrieved information with Ciurczak's diagnostic testing device to provide a more comprehensive

glucose monitoring device. This would continue to help improve the quality of self-medical care for diabetic patients.

34. Claim 11:

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation, but Wilcox discloses *wherein recording a voice message comprises: receiving said voice message; converting said voice message into digital samples; and storing said digital samples* (see at least Fig. 3, ¶0017). In this reference, the stored digital sample is the finalized electronic report. It would have been obvious to a person having ordinary skill in the art at the time of invention to combine Wilcox's stored samples with Ciurczak's diagnostic testing device to provide a more comprehensive glucose monitoring device. This would continue to help improve the quality of self-medical care for diabetic patients.

35. Claim 22, 23 and 24:

Ciurczak discloses the limitations as shown in the rejections above. Ciurczak does not disclose the following limitation, but Wilcox discloses:

- *further comprising a user interface for receiving at least one user instruction for operating said medical diagnostic testing device* (Wilcox, see at least ¶0009).

- *wherein said at least one user instruction includes a record instruction, wherein said medical diagnostic testing device records said voice message in response to said record instruction (Wilcox, see at least Fig. 3, ¶0009).*
- *wherein said at least one user instruction includes a retrieve instruction, wherein said medical diagnostic testing device displays a stored test result and plays a recorded voice message associated with said stored test result in response to said retrieve instruction (Wilcox, see at least Fig. 2, ¶0009, ¶0016).*

In this reference, the computer is the testing device, the computer program is the means to receive instructions, the study is the test result and images are interpreted using voice recognition software. It would have been obvious to a person having ordinary skill in the art at the time of the invention to combine Wilcox's instructions and recorded voice message with Ciurczak's diagnostic testing device to provide a more comprehensive glucose monitoring device. This would continue to help improve the quality of self-medical care for diabetic patients.

36. Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilcox (US 20050002483 A1) in view of Official Notice.

37. Claim 26 and 28:

Wilcox discloses limitations as shown in the rejections above. Wilcox does not disclose *wherein said audio system includes a microphone for receiving said voice message and wherein said audio system includes a speaker for playing said recorded voice message*. However, the Examiner takes **Official Notice** that it is old and well-known in the electronics arts that the components, used in audio systems, are microphones and speakers, and recorders. It would have been obvious to a person having ordinary skill in the art at the time of invention to combine audio components with Wilcox's diagnostic testing device to provide a more comprehensive glucose monitoring device. This would continue to help improve the quality of self-medical care for diabetic patients.

38. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ciurczak (US 2002019367 A1) in view of Official Notice further in view of Cunningham (US 6,306,104 B1).

39. Claim 16

Ciurczak and Official Notice disclose the limitations as shown in the rejections above. Ciurczak and Official Notice do not disclose the following limitation, but Cunningham discloses *wherein said test result is a glucose level in said sample* (see column 1, lines 41-48). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Cunningham's glucose level results with Ciurczak's medical diagnostic testing device to provide

the basic glucose concentration in the blood stream of diabetic patients. This would continue to help improve the quality of self-medical care for diabetic patients.

Conclusion

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Teresa Woods** whose telephone number is **571.270.5509**. The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JAMES A. REAGAN** can be reached at **571.272.6710**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair> . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

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Art Unit: 4114

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Examiner, Art Unit 4114

/James A. Reagan/

Supervisory Patent Examiner, Art Unit 4114